Food and Drug Administration Establishment Inspection Report

Date Assigned: 07/02/2002 **Inspection Start Date:** 07/08/2002 **Inspection End Date:** 07/11/2002

Firm Name & Address: Conceptus Inc , 1021 Howard Ave San Carlos, CA 94070 US

Firm Mailing Address: 1011 Mccarthy Blvd, Milpitas, CA 95035-7920 United States

FEI: 1000221357 **JD/TA:** 14 **County:** SANTA CLARA **Est Size:** (b) (4)

Phone: (650)962-4000 **District:** SAN-DO **Profiled:** Yes

Conveyance Type: **% Interstate:** (b) (4) **Inspectional Responsibility:** Field

Endorsement

FACTS Assignment # 319482

Gerald N. McGirl, D.D.S., ORA/ORO/DFI, and Barbara A. Crowl, CDRH/OC/DBM, conducted a Directed PMA Data Audit Sponsor/Contract Research Organization/Monitor inspection/audit of Conceptus Incorporated.

This inspection/audit was conducted in accordance with CP 7348.810, based on a 17 Jun 2002 assignment from CDRH/OC/DBM, HFZ-311. The assignment requested coverage of the firm's sponsor/monitor activities related to clinical studies of the Essure Permanent Birth Control System, conducted under (b) (4) (Phase II) and (b) (4) (Pivotal). Conceptus has submitted data from (b) (4) EssureTM (formerly known as the STOP device) system clinical studies to FDA in support of PMA P020014.

Monitoring procedures are adequate. Monitoring visits were conducted more frequently than required by the Conceptus SOPs. On 11 Jul 2002, form FDA-483, Inspectional Observations, was issued to Steven R. Bacich, President and CEO, noting that unscheduled visit adverse events were not reported in the PMA.

All inspectional information was provided. There were no refusals.

Correspondence regarding this inspection should be directed to Steven R. Bacich, President and CEO, at the above address. Copies of correspondence should be sent to Cindy Domecus, Senior Vice President of Clinical Research and Regulatory Affairs, at the same address.

Suggested classification: VAI. Refer to CDRH/OC/DBM, HFZ-311 (Barbara A. Crowl) for final review and classification. Re-inspect per Center assignment.

Distribution:
Original + Exhibits: SAN-DO File (CFN 29-51250)
CC: CDRH/OC/DBM, HFZ-311 (Barbara A. Crowl)
CS + Copy of Assignment + 483: SAN-DO BiMo Coordinator (Rochelle B. Young)
CS + EIR: FMD-145 File

Endorsement Location: SAN-DO File & HFZ-310

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Gerald N McGirl	07/12/2002 03:10 PM ET		ET

Food and Drug Administration Establishment Inspection Report

Date Assigned: 06/23/2003 **Inspection Start Date:** 06/25/2003 **Inspection End Date:** 07/07/2003

Firm Name & Address: Conceptus Inc , 1021 Howard Avenue San Carlos, CA 94070 US

Firm Mailing Address: 1011 Mccarthy Blvd, Milpitas, CA 95035-7920 United States

FEI: 1000221357 **JD/TA:** 14 **County:** SANTA CLARA **Est Size:** (b) (4)

Phone: (650)962-4000 **District:** SAN-DO **Profiled:** Yes

Conveyance Type: **% Interstate:** (b) (4) **Inspectional Responsibility:** Field

Endorsement

This was a postmarket approval inspection of Conceptus, done as a Level 2 QSIT evaluation of 4 major subsystems. The firm manufactures a device for female sterililization. The previous inspection of 7/9/2002 found departures from the QSR relating to design controls and CAPA. Approval of the PMA occurred on 11/04/02.

During this current inspection the investigator found 2 departures from QSR. Non-conforming raw materials and subassemblies are not recorded on the Lot History Records. Also, SOPs were not being followed for control of non-conforming products.

Firm managment agrees with the observations, and wishes to make a written response to the agency regarding corrections.

VAI: routine FU

o: SAN
cc: SJRP
cs: APS
cs & 483: FDB Barbara Moynier

Endorsement Location: SAN-DO

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Mark E Chan	07/10/2003 01:37 PM ET	Andrea P Scott	07/21/2003 01:04 PM ET
Mark E Chan	07/10/2003 01:36 PM ET		ET
Mark E Chan	07/09/2003 06:24 PM ET		ET

Food and Drug Administration Establishment Inspection Report

Date Assigned: 06/25/2008 **Inspection Start Date:** 07/09/2008 **Inspection End Date:** 07/11/2008

Firm Name & Address: Conceptus Inc , 331 E Evelyn Ave Mountain View, CA 94041-1530 US

Firm Mailing Address: 1011 Mccarthy Blvd, Milpitas, CA 95035-7920 United States

FEI: 1000221357 **JD/TA:** 14 **County:** SANTA CLARA **Est Size:** (b) (4)

Phone: (650)962-4000 **District:** SAN-DO **Profiled:** Yes

Conveyance Type: **% Interstate:** (b) (4) **Inspectional Responsibility:** Field

Endorsement

This Level 1 QSIT inspection of Conceptus, Inc., Mountain View, Ca, a manufacturer of Permanent Sterilization Devices, was conducted in accordance with FACTS Assignment #929966 a routine assignment. The previous inspection of 9/21-22/2005 was classified NAI; the investigator noted no observations.

During the current inspection the investigator covered CAPA and Design Controls for Essure model ESS305. The investigator observed no issues. No FDA-483 was issued.

Classification: NAI
F/U: Routine

o: SAN-DO
cc: SJ-RP, CCC (Mfg. Codes)
IAS & 483: FDB (B. Moynier)
narrative: FMD-145 (DCB)

Endorsement Location: FACTS, SAN-DO, SJRP Files

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Timothy C Grome	07/23/2008 06:24 PM ET	Gary L Zaharek	08/15/2008 05:21 PM ET

Food and Drug Administration Establishment Inspection Report

Date Assigned: 12/20/2010 **Inspection Start Date:** 12/08/2010 **Inspection End Date:** 01/06/2011

Firm Name & Address: Conceptus, Inc. , 331 E.Evelyn Ave. Mountain View, CA 94041 US

Firm Mailing Address: 1011 Mccarthy Blvd, Milpitas, CA 95035-7920 United States

FEI: 1000221357 **JD/TA:** 14 **County:** SANTA CLARA **Est Size:** (b) (4)

Phone: (650)962-4000 **District:** SAN-DO **Profiled:** Yes

Conveyance Type: **% Interstate:** (b) (4) **Inspectional Responsibility:** Field

Endorsement

This inspection of Conceptus, Inc., Mountain View, CA , a manufacturer of Essure Permanent Birth Control System, was conducted in accordance with FACTS Assignment 1246754. This was a For Cause assignment to follow up on findings of an FDA foreign inspection of the firm's contract manufacturer, (b) (4) That inspection found that Conceptus, Inc. had (b) (4) (b) (4) lots of their product fail specification testing. The previous inspection of Conceptus, Inc., Mountain View, CA on 7/9-11/2008 was classified NAI; the investigator noted no observations.

During the current inspection the investigator covered Management Controls, Design Controls, CAPA, supplier qualification, and Medical Device Reporting. During this inspection the investigator observed issues with MDR reporting, Risk Analysis, and CAPA initiation. An FDA-483 was issued noting these concerns. Management corrected the CAPA documentation and promised correction of the Risk Analysis, and changed the MDR reporting classification of a complaint of pain from a loose coil that was found in the peritoneal (abdominal-pelvic) cavity that required surgical removal.

Management did not agree to report complaints of injuries from other manufacturer's devices or complaints of malfunctions in which the micro-insert coil was seen in the peritoneal cavity but no complaintas of pain had been reported to date. After a complete review by OSB of two complaints of injury sustained by another manufacturer's instruments during Essure placement procedure, OSB did not agree with citing those two complaints on the FDA-483. (See Attachement #5) OSB still supports complaints of loose micro-insert coils in the peritoneal (abdominal-pelvic) cavity, being reportable malfunction complaints. Will reinspect in 4 months.

Classification: VAI
F/U: 4 months

o: SAN-DO
c: SJ-RP, HQ Unit Contact: Brenda S. Lucas, OSB/DPS
Mfg. Codes Pg(s) Only: CCC
IAS & 483: FDB (H. Loui)
Narrative Only: FMD-145 (DCB)

Endorsement Location: SAN-DO, SJRP files, FACTS

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Timothy C Grome	02/28/2011 01:24 PM ET	Ruark Lanham	03/04/2011 04:42 PM ET
Timothy C Grome	02/23/2011 01:26 PM ET		ET
Timothy C Grome	02/23/2011 01:25 PM ET		ET
Timothy C Grome	02/05/2011 10:54 PM ET		ET
Timothy C Grome	01/10/2011 06:35 PM ET		ET

Food and Drug Administration Establishment Inspection Report

Date Assigned: 06/04/2013 **Inspection Start Date:** 05/30/2013 **Inspection End Date:** 06/26/2013

Firm Name & Address: Conceptus, Inc. , 331 E Evelyn Ave Mountain View, CA 94041-1530 US

Firm Mailing Address: 1011 Mccarthy Blvd, Milpitas, CA 95035-7920 United States

FEI: 1000221357 **JD/TA:** 14 **County:** SANTA CLARA **Est Size:** (b) (4)

Phone: (650)962-4000 **District:** SAN-DO **Profiled:** Yes

Conveyance Type: **% Interstate:** (b) (4) **Inspectional Responsibility:** Field

Endorsement

This Level 1 QSIT inspection of Conceptus, Inc., Mountain View, CA, a manufacturer of Essure permanent contraceptive implant coils, was conducted in accordance with FACTS Assignment 8676539, a FY13 workplan assignment. The previous inspection of De12/08/2010 to 01/06/2011 was classifiedVAI; the investigator noted observations with MDR reporting, CAPA documentation, and Design Risk Assessment.

During the current inspection the investigator covered Complaint Handling, CAPA and Design Control. Observations noted during the previous inspection were verified corrected. Correspondence between firm and CDRH was viewed that states complaints of implant coil located inside abdominal cavity outside of fallopian tubes do not have to be reported as MDRs unless the patient is experiencing pain and requires surgical removal of the coils. Complaints of Uterine pregnancy do not have to be reported as MDRs (b) (4), (b) (5)
(b) (4), (b) (5)

During this inspection the investigator observed no issues and no FDA-483 was issued.

Classification: NAI
F/U: Routine

o: SAN-DO
c: San Jose-RP (electronic copy)
Mfg. Codes Pg(s) Only: CCC
IAS: FDB (H. Loui)
Narrative Only: FMD-145 (L. Kraai)

Endorsement Location: FACTS, SAN-DO file

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Timothy C Grome	07/23/2013 08:45 PM ET	Eric W Anderson	11/07/2013 09:38 PM ET

Food and Drug Administration Establishment Inspection Report

Date Assigned: 10/28/2014 **Inspection Start Date:** 04/27/2015 **Inspection End Date:** 07/01/2015

Firm Name & Address: 9 ayer Healthcare LLC , 1011 McCarthy Blvd Milpitas, CA 95035-7920 US

Firm Mailing Address: 1011 McCarthy Blvd, Milpitas, CA 95035-7920 United States

FEI: 3010620490 **JD/TA:** 14 **County:** SANTA CLARA **Est Size:** Unknown

Phone: **District:** SAN-DO **Profiled:** No

Conveyance Type: **% Interstate:** **Inspectional Responsibility:**

Endorsement

This sponsor inspection of Bayer HealthCare LLC, Milpitas, CA, a sponsor of a clinical study involving the firm's device Essure (b) (4) (b) (4), was conducted in accordance with FACTS Assignment # 11468333, a directed assignment by CDRH Division of Bioresearch Monitoring.

The previous inspection of date was a Quality Systems inspection and was classified (NAI).

During the current inspection the investigator covered areas specific to the studies. Records for studies were searched for information related to complaints of study subjects who were enrolled in 2001 to 2003. Not all complaintants could be identified from the study records. Design Control information was collected as per CDRH request. During this inspection the investigator observed no issues.

Recommended Classification: NAI
F/U: Routine

o: SAN-DO
c: SJo-RP, CDRH/OC/Div. BiMo (J. Collins-Mitchell)
Mfg. Codes Pg(s) Only: CCC
c/s only: SAN-DO BIMO Monitor (L. Capron)
Narrative Only: FMD-145 (L. Kraai) after review by CDRH

Endorsement Location: SAN-DO file, FACTS

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Thea C Grome	08/27/2015 07:32 PM ET	Matthew A Walburger	09/08/2015 03:29 PM ET
Thea C Grome	08/27/2015 07:29 PM ET		ET